

**CAREONE NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet, film coated**  
**American Sales Company**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**American Sales Company NIGHTTIME SLEEP AID Drug Facts**

**Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Use**

for relief of occasional sleeplessness

**Warnings**

**Do not use**

- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

**Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers

**When using this product**

- avoid alcoholic drinks
- drowsiness may occur
- do not drive a motor vehicle or operate machinery

**Stop use and ask a doctor if**

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children. Overdose warning:**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Directions**

adults and children 12 years and over	take 2 caplets at bedtime if needed, or as directed by a doctor
children under 12 years	do not use

**Other information**

- **each caplet contains:** calcium 15 mg
- store at 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- **do not use if blister unit is broken or torn**

**Inactive ingredients**

carnauba wax, crospovidone, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Compare to the active ingredient in Simply Sleep<sup>®</sup> Nighttime Sleep Aid

NIGHTTIME SLEEP AID

Diphenhydramine HCl, 25mg

Does Not Contain Pain Reliever

Helps you fall asleep

Non Habit-Forming

Actual Size

Gluten Free

OUR PHARMACISTS RECOMMEND

24 CAPLETS

CAREone™

# NIGHTTIME SLEEP AID

## Diphenhydramine HCl, 25mg

CAREone™

NDC 41520-431-62

Compare to the active ingredient in  
Simply Sleep® Nighttime Sleep Aid\*

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### 24 CAPLETS

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\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Simply Sleep® Nighttime Sleep Aid.



## CAREONE NIGHTTIME SLEEP AID

diphenhydramine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-431
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE (Light Blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	L431
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-431-62	12 in 1 CARTON	04/13/2004	

1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41520-431-67	24 in 1 CARTON	08/08/2008	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part338		04/13/2004	

**Labeler** - American Sales Company (809183973)

Revised: 3/2019

American Sales Company